UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO 01-CV-12257-PBS and 01-CV-339	Judge Patti B. Saris

TRIAL OF CLASS 2 AND 3 CLAIMS

MEMORANDUM OF LAW IN SUPPORT OF THE JOHNSON & JOHNSON DEFENDANTS' MOTION FOR JUDGMENT ON PARTIAL FINDINGS

Johnson & Johnson, Centocor, Inc. and Ortho Biotech Products, L.P. ("the J&J Defendants") respectfully submit this memorandum of law in support of their motion for judgment on partial findings pursuant to Rule 52(c) of the Federal Rules of Civil Procedure. As the First Circuit noted in Morales Feliciano v. Rullan, 378 F.3d 42, 59 (1st Cir. 2004), "[w]hen a party has finished presenting evidence and that evidence is deemed by the trier insufficient to sustain the party's position, the court need not waste time, but, rather, may call a halt to the proceedings and enter judgment accordingly." See also 9A Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 2573.1 (2d ed. 1994).

I. THE J&J DEFENDANTS SHOULD BE GRANTED JUDGMENT ON PARTIAL FINDINGS

A. Procrit®

Class 3

Plaintiffs admit that there is no liability for Class 3 for Procrit, because the "spreads" on Procrit were always below 30%. (Berman, Nov. 6 Tr. at 28:13-15; see also Written Direct Testimony of Raymond S. Hartman ("Hartman Direct") at Attachments G.3.c and I.3; Hartman, Nov. 21 Tr. at 121:13-122:3). Dr. Rosenthal acknowledged that Procrit, because of its modest spreads, is one of the hundreds of physician-administered drugs and thousands of self-administered drugs for which the AWP-based reimbursement system "works." (Rosenthal, Nov. 27 Tr. at 69:21-70:25).

Class 2

Plaintiffs' sole basis for keeping Procrit in Class 2 is their "per se liability" theory. Defendants' group response addresses the failings of this theory. Indeed, under that theory, every single prescription drug sold in the United States throughout the entire class period (and

thereafter) has violated Massachusetts law, notwithstanding plaintiffs' admission that AWP-based reimbursement "works" for "99 percent" of those drugs. (Rosenthal, Nov. 27 Tr. at 69:21-70:16; 83:20-24). In fact, as Dr. Hartman admits, if the Court were to apply a 30% liability threshold for Class 2, there would be no liability or damages for Procrit. (Plaintiffs' Exhibit 4008; Hartman, Dec. 11 Tr. at 98:1-6).

As noted above, Dr. Rosenthal admitted that Procrit was within the "99 percent" of drugs for which an AWP reimbursement system worked just fine. Not only were Procrit's spreads within what plaintiffs' claim was the "market's expectation," Procrit was one of the drugs specifically discussed in the 1997 OIG report on the difference between acquisition cost and AWP. (Defendants' Exhibit 1075 at B-2 and B-3). Payors, therefore, had information concerning the small discounts offered on Procrit. (Id.; Dooley, Nov. 16 Tr. at 64:5-65:10; Hartman, Nov. 21 Tr. at 123:6-124:3).

Accordingly, judgment should be entered as to Procrit in regards to Classes 2 and 3.

B. Remicade®

Class 2

As with Procrit, plaintiffs admit that if the Court were to apply a 30% liability threshold for Class 2, there would be no liability or damages for Remicade. (Plaintiffs' Exhibit 4008; Hartman, Dec. 11 Tr. at 98:1-6).

Moreover, as described below, plaintiffs admit that Remicade's spreads are completely inconsistent with plaintiffs' liability theory. Remicade was sold at its published WAC producing a predictable relationship between Remicade's AWP and its selling price. No discounts were given to physicians and when Centocor sought a "J-code" from Medicare, it

provided Medicare with Remicade's AWP and WAC – numbers that plaintiffs admit were published. (Plaintiffs' Exhibit 261; Hoffman, Nov. 14 Tr. at 88:19-89:5).

Class 3

Plaintiffs admit that there is no liability for Class 3 for Remicade in 1998, 2000, 2002, and 2003, because the "spreads" on Remicade in those years were 30% or less. (Hartman Direct at Attachments G.3.c and I.3). Plaintiffs assert liability as to Remicade solely for 1999 and 2001 based on Dr. Hartman's calculation of Remicade's "spread" in those years of 32.1% and 31.9%, respectively. (Id.; Hartman, Nov. 21 Tr. at 128:5-8). The cross of plaintiffs' experts demonstrated that no reasonable factfinder could find a violation of 93A based on Hartman's 1999 and 2001 spread calculations.

1. The So-Called "AWP Scheme" Alleged by Plaintiffs is Completely Inapplicable to Remicade.

Plaintiffs' experts contend that the AWP scheme involves: (1) opaque pricing because of "secret" discounting to doctors; (2) the lack of a predictable relationship between AWP and ASP and (3) increasing spreads to drive market share. (See, e.g., Written Direct Testimony of Dr. Meredith Rosenthal at ¶¶ 71-74; Hartman Direct at ¶¶ 21-25, 92.)

On cross, plaintiffs' experts admitted the obvious – none of these theories apply to Remicade. Plaintiffs admit that the "published" (i.e., public) spread between Remicade's list price and its AWP was 30%.[1] Dr. Hartman admitted that the published Remicade 30% spread between AWP and WAC was not secret. (Hartman, Nov. 21 Tr. at 129:2-130:5). Plaintiffs

[1] See Defendants' Exhibit 2782, Plaintiffs' Supplemental Response to the J&J Defendants' Requests for Admission and Interrogatories Concerning Remicade® (Dec. 13, 2005) ("Response to Request to Admit and Interrogatories"), Response to Request to Admit No. 2 (Request: "Admit that from 1998 to the present, the published AWP for Remicade® has been 130% of the published WAC for Remicade®." Response: "Admitted.") (emphasis added).

further admit that Centocor did not offer discounts or rebates to physicians. (Rosenthal, Nov. 27 Tr. at 77:19-21; Hartman, Nov. 21 Tr. at 131:17-132:26; see also Hoffman, Nov. 14 Tr. at 89:2-8). Given the foregoing, Dr. Rosenthal admitted that Remicade's pricing was "transparent." (Rosenthal, Nov. 27 Tr. at 77:3-21).

Dr. Rosenthal also admitted that there was a predictable relationship between Remicade's AWP and ASP. (Rosenthal, Nov. 27 Tr. at 82:12-14). She acknowledged that "[t]he average spreads [for Remicade] over the Damage Period were approximately 30 percent," (Rosenthal Direct, ¶ 50) (emphasis added), and that the AWP system works for drugs within Dr. Hartman's 30% liability threshold. (Rosenthal, Nov. 27 Tr. at 70:21-25). Finally, Remicade's pricing history is directly inconsistent with plaintiffs' theory of incentives regarding the spread between AWP and ASP. (See, e.g., Hartman Direct at ¶ 30; see also Rosenthal, Nov. 27 Tr. at 71:1-6 (stating her opinion that ASP and AWP should "track but certainly not [be] equal.") In fact, Dr. Hartman's spread calculations (assuming they are correct) contradict plaintiffs' theory altogether. Remicade's sales grew in the years when he says the spread got smaller. (See Rosenthal, Nov. 27 Tr. at 88:1-21; Hoffman, Nov. 14 Tr. at 117:21-24).

2. There Is No 30% "Bright Line" Payor Expectation.

Plaintiffs submitted no evidence that there is an absolute "bright-line test" or "speed limit" that payors thought would never be exceeded for any drug by even a modest amount. (Hartman, Nov. 21 Tr. at 130:21-25, 135:12-136:3). Dr. Hartman points to no contemporaneous 30% "speed limit" to which payors looked. His "analysis" – such as it is – is a retrospective review of a limited number of articles discussing prices of self-administered and physician-administered drugs from which he purports to derive a class-wide expectation of the "average" spread between AWP and ASPs for drugs sold in the United States. (See Hartman, Nov. 20 Tr. at 78:17-25, 18:1-9).

Accordingly, even if one accepts, for purposes of this motion, that 30% is a reasonable approximation of the spreads payors expected during the class period, there is no proof that payor expectations were so finely-tuned as to distinguish between spreads of 30% and 31.9%. (See Hartman, Nov. 21 Tr. at 131:13-16). Dr. Rosenthal acknowledged this self-evident point in her own direct. She characterized the Remicade spreads, which Dr. Hartman said ranged from 28.5% to 32.1%, as "approximately 30 percent." (Rosenthal Direct at ¶ 50).

On cross, even Dr. Hartman acknowledged the folly of a "bright line" test. He admitted that during the class period the market would have been aware of discounts and rebates beyond the AWP/WAC spread. (Hartman, Nov. 21 Tr. at 22:18-25, 19:1-3; see also Hartman Direct at ¶¶ 91-92). He further admitted that under his "bright line" test, if a manufacturer offered a 3.8% discount/rebate on a drug with a published 25% WAC-to-AWP spread, the manufacturer would be at his 30% speed limit. (Hartman, Nov. 21 Tr. at 7-11). He then acknowledged that if the discount/rebate moved from 3.8% to 4.0%, this 0.2% move would, under his theory, make a manufacturer liable under 93A for having engaged in "fraudulent" conduct. (Hartman, Nov. 21 Tr. at 135:12-136:3). There is zero evidence to support the fine line Dr. Hartman seeks to draw.

3. Dr. Hartman's Math for 1999 and 2001.

Dr. Hartman calculated his spreads by comparing the average selling price for all sales during the year with the AWP in effect as of June 30th. (Hartman, Nov. 21 Tr. at 136:21-25; 139:10-11). He did not use average AWPs even where there were two or more AWPs in effect during a year. (Id. at 138:7-10). This resulted in spreads slightly in excess of 30% for 1999 and 2001.

The reason is simple. Centocor took price increases on June 18, 1999 and on June 6, 2001.[2] As a result of the 1999 price increase, Remicade's WAC went from $450.00 to $470.25, with a corresponding increase in its AWP from $585.00 to $611.33. Similarly, the 2001 price increase resulted in a change in WAC from $512.04 to $532.00, and a corresponding increase in AWP from $665.65 to $691.61. The average selling prices in those years, according to Dr. Hartman, were $462.77 and $524.32, respectively. (Hartman Direct at Attachment G.3.a).

Dr. Hartman could have calculated his spreads by comparing the average selling prices to an average AWP for the year. Instead, he calculated his spreads based on the higher AWPs in effect on June 30th. As a result, all sales made at the lower WAC in effect during the first part of 1999 and 2001 were paired with the higher AWPs in effect during the second part of those years. Not surprisingly, this pairing inaccurately pushed the spreads in those two years slightly over his 30% limit (Hartman, Nov. 21 Tr. at 139:19-24):

	1999	**2001**
June 30th AWP	$611.33	$691.61
Hartman ASP	$462.77	$524.32
Difference (% Spread)	$148.56 (32.1%)	$167.29 (31.9%)

Calculating the spread by comparing Dr. Hartman's ASP to the average of the two AWPs in effect in 1999 and 2001, produces what he found in every other year – Remicade spreads of 30% or less[3]:

---

[2] Defendants' Exhibit 2782, Response to Request to Admit and Interrogatories, Response to Interrogatory No. 9, Exhibit A (reflecting WAC and AWP increases on June 18, 1999 and June 6, 2001). (See also Hartman, Nov. 21 Tr. at 136:21-137:22; Plaintiffs' Exhibit 825 (Remicade Pricing History)).

[3] An "average AWP" is calculated by adding together the two AWPs in effect during a year and dividing by 2. Thus, the "average AWP" in 1999 was $598.17. That figure is calculated by adding

(Footnote Continued)

	1999	2001
Average AWP	$598.17	$678.63
Hartman ASP	$462.77	$524.32
Difference (% Spread)	$135.40 (29.3%)	$154.31 (29.4%)

No doubt anticipating cross examination, Dr. Hartman acknowledged on direct that his spread calculations yield only approximate damage figures that "more or less" reflect the "order of magnitude of the quantity you're looking at" (Hartman, Nov. 20 Tr. at 31:8-14).

Accordingly, based on simple math, the spreads for Remicade, even for 1999 and 2001, are within Dr. Hartman's 30% "speed limit."

4. There is No Causation.

Plaintiffs submitted no evidence that BCBS/MA or other Class 3 payors would have lowered their reimbursement for Remicade had they known that the spreads in 1999 and 2001 may have been about 1-2% higher than the 30% spread Dr. Hartman claims the market anticipated for physician-administered drugs. To the contrary, BCBS/MA admitted that it did not lower reimbursement on any physician-administered drugs despite knowledge of "grossly inflated" spreads. (Devaux, Nov. 7 Tr. at 137:16-24, 152:7-11, see also Mulrey, Nov. 8 Tr. 28:24-29:15).

Accordingly, judgment should be entered as to Remicade in regard to Class 2 and Class 3.

$585.00 to $611.33 ($1196.33) and dividing by 2. Similarly, in 2001, the "average" AWP is $678.63, calculated by adding $665.65 and $691.61 ($1357.26) and dividing by 2. Although it is not necessary to consider the testimony of Mr. Dukes in deciding this motion, he showed that the use of "weighted average AWPs" instead of " average AWPs" also yields spreads that are less than 30%. (Dukes, Dec. 11 Tr. at 109:25-110:5; Trial Declaration of Jayson S. Dukes at ¶ 28).

Conclusion

Neither Procrit nor Remicade fits the "AWP scheme" alleged here and the numbers confirm it. The J&J Defendants' motion for judgment should be granted.

Dated: December 18, 2006

/s/ William F. Cavanaugh, Jr.

William F. Cavanaugh, Jr.
Andrew D. Schau
Erik Haas
Adeel A. Mangi
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036-6710
(212) 336-2000

Certificate of Service

I certify that a true and correct copy of the foregoing was served on all parties on December 18, 2006 via LEXIS/NEXIS.

/s/ Andrew D. Schau
Andrew D. Schau